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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,516	09/21/2005	Hans W. Schmid	2923-708	2283

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WASHINGTON, DC 20005

EXAMINER

MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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09/13/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/533,516	Applicant(s) SCHMID, HANS W.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6-24-10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on June 18, 2010 is acknowledged. Claims 1-13 and 20-29 are pending in this application. Claims 1-13 remain withdrawn from consideration.

Newly submitted claim 28 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant has presented a method drawn to a distinct patient population which had been presented originally would have been subject to a restriction requirement.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 28 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on June 24, 2010 is acknowledged. A signed copy is attached to this office action.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierpaoli et al. (US Patent 4,746,674) in view of Noser et al. (US 2002/0034485) and further in view of Kondo et al. (JP410287531A, Abstract).

Pierpaoli discloses a method of treating the skin and/or scalp of a human host by the administration of a melatonin composition in order to improve the cosmetic or physical appearance of the skin and/or scalp (abstract). The composition is disclosed as being topically applied to the skin (column 1, lines 8-11). Pierpaoli discloses the composition is used for the rejuvenation of partially degenerated hair follicles through the use of melatonin compounds, homologues, and derivatives (column 1, lines 20-21).

Regarding claim 21, the composition can be used for the treatment of drug induced or toxic alopecia (column 11, lines 40-43).

Regarding claims 22-23, the disclosure of humans encompasses both men and women.

Regarding claims 24-25, the relative concentration of melatonin is 10^{-4} to 1% of an ointment (column 12, lines 63-65). It is additionally disclosed that the amount of melatonin administered can be altered based on the individual and the specific needs of that individual (column 7, lines 42-45).

Pierpaoli does not disclose the use of biotin or ginkgo biloba.

Noser discloses hair tonic for prevention or treatment of hair loss comprising biotin (abstract).

The combination of Pierpaoli and Noser do not disclose the use of ginkgo biloba.

Kondo discloses a cosmetic formulation comprising ginkgo biloba (abstract).

The skilled artisan would have a reasonable expectation of making a composition comprising melatonin, ginkgo biloba and biotin since the cited references all disclose the therapeutic properties of each component.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated ginkgo biloba and biotin into the composition of Pierpaoli because Kondo discloses ginkgo biloba promotes and normalizes the function of hair and head skin and makes them healthy and Noser discloses the use of biotin influences the quality of the hair positively. Biotin is the vitamin of keratinization, (i.e. an improved supply of biotin to the hair organ improves keratinization). Biotin particularly increases the strength and tear resistance and generally the resistance of hair to outside or environmental influences and stressful treatments in the case of fine hair but also significantly for normal hair. Biotin strengthens the anchoring of the bottom of the hair in the scalp. As a result there is a decrease in the number of hairs falling out and the number lost is stabilized at a minimum value (paragraph 0024-0025).

Furthermore, it has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having

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been individually taught in prior art. Therefore, since each of the references teaches melatonin, biotin, and ginkgo are effective ingredients in compositions for the treatment of hair loss, it would have been obvious to combine them with the expectation that such a combination would be effective in promoting hair growth. Thus, combining them flows logically from their having been individually taught in prior art.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues:

***The Noser reference requires the use of a C10-C18 fatty acid or salt thereof and biotin is ineffective without it.**

The Examiner respectfully disagrees. There is no teaching in the Noser reference that biotin would not function as recited in the absence of the fatty acid. Noser discloses the advantages of biotin, as discussed above, to increase the strength and tear resistance of hair. Additionally, Noser discloses the fatty acid as an excipient or a carrier and not as an active agent; therefore, its inclusion is still encompassed by the instant claims. He does not disclose the fatty acid has any effect on the growth or condition of the hair. Therefore, the skilled artisan would expect that when the biotin is added to the Pierpaoli's melatonin composition, it would function as recited in Noser. Applicant has not presented any arguments regarding the teachings of Kondo.

***Hanada teaches that biotin is effective only when combined with certain specific compounds.**

Comment [RAW1]: This does not characterize applicant's argument very well. What about the Hanada reference? You don't address that at all. If the new matter makes the claims allowable then you drop the rejection and deal with the claims as written. Once the new matter is removed you can reinstate the rejection.

The Examiner respectfully disagrees. After a review of the Hanada reference, the Examiner was unable to find a teaching that biotin is ineffective without the specific compounds disclosed by Hamada.

The rejection is therefore maintained.

Newly Applied Rejections

Claim Rejections - 35 USC § 112

Claims 20-27 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claim 20 to recite the only active agent is melatonin or its derivatives. However, after thorough review of the specification, the Examiner was unable to locate support for such an amendment. The specification indicates that the instant method requires the use of the combination of the 3 recited components of melatonin, biotin and ginkgo biloba are required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Melissa S Mercier/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1617